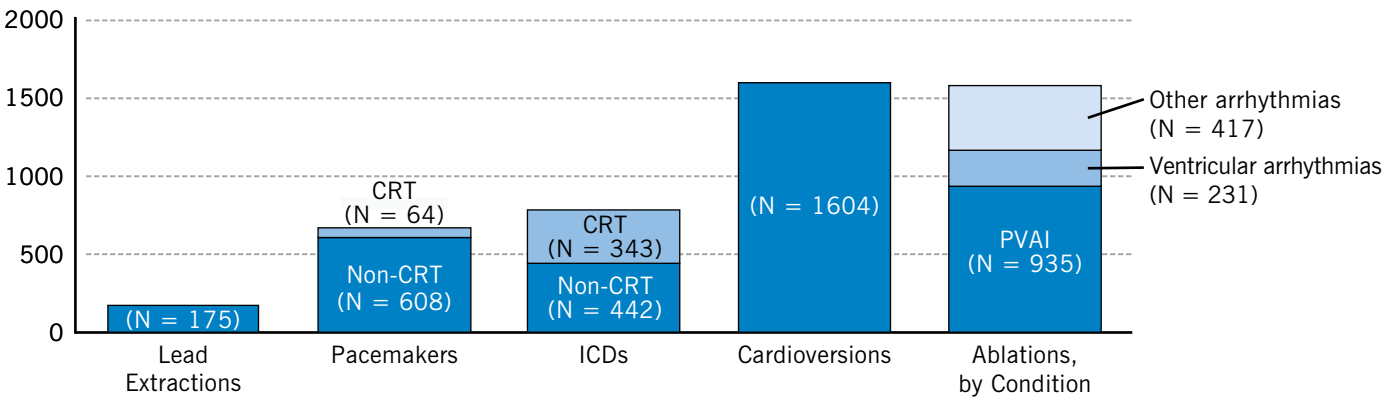
Electrophysiology Laboratory Procedures by Type (N = 5445)[a]

Cleveland Clinic electrophysiologists use specialized approaches to diagnose and treat patients with a wide variety of arrhythmias. They are noted for their expertise in ablation procedures and management of patients with pacemakers and defibrillators.

2016

Volume

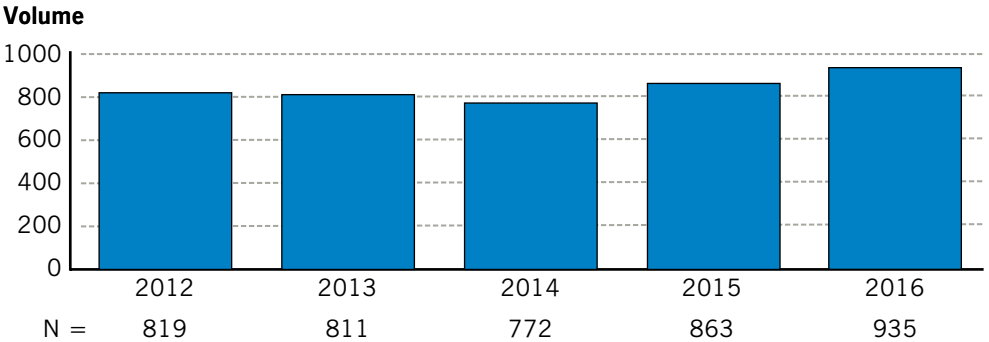


CRT = cardiac resynchronization therapy, ICD = implantable cardioverter defibrillator, PVAI = pulmonary vein antrum isolation

[a]The total number of procedures includes left atrial appendage occlusion procedures, electrophysiology studies, ICD testing, temporary pacers, loop recorders, and electrophysiology special procedures (endomyocardial biopsy, esophageal pacing, right heart catheterization, venography, and others). These are not included in the graph.

Pulmonary Vein Antrum Isolation Procedures (N = 4200)

2012 – 2016



Pulmonary vein antrum isolation (PVAI) essentially disconnects the pathway of the abnormal heart rhythm and prevents atrial fibrillation.

Success Rates

Success is defined as a restored sinus rhythm without recurrence of atrial fibrillation (AF) after the patient has stopped taking antiarrhythmic medications for at least 12 months after the procedure. This is influenced by a number of factors, including the length of time the patient has been in AF and the presence or absence of underlying heart disease.

In a recent study[1] of 831 patients who underwent pulmonary vein antrum isolation at Cleveland Clinic, 81% of patients with paroxysmal AF were arrhythmia-free while off antiarrhythmic drugs at 12 months postablation. Paroxysmal AF is defined as AF that terminates within days without cardioversion. A total of 7.8% of this patient population had AF after 1 year postablation (late-recurrence AF).

The success rate is lower for patients with persistent or long-standing persistent AF (65% for a single ablation procedure) and is affected by the presence of valvular heart disease or other underlying problems.

A total of 161 patients who had early recurrence of AF had a repeat ablation procedure. At 14 months after repeat ablation, 78.9% were arrhythmia-free while off antiarrhythmic drugs. Of the 27 patients who had late-recurrence AF and a repeat ablation, 74.1% were arrhythmia-free while off antiarrhythmic drugs at 17 months after repeat ablation.

Reference

1. Hussein AA, Saliba WI, Martin DO, Bhargava M, Sherman M, Magnelli-Reyes C, Chamsi-Pasha M, John S, Williams-Adrews M, Baranowski B, Dresing T, Callahan T, Kanj M, Tchou P, Lindsay BD, Natale A, Wazni O. Natural history and long-term outcomes of ablated atrial fibrillation. *Circ Arrhythm Electrophysiol*. 2011 Jun;4(3):271-278.`

Complications of PVAI

2016

Complication	N	Percent	Benchmark Rate[1] (%)
Death	0	0	0.15
Tamponade	5	0.53	1.31
Pneumothorax	0	0	0.09
Hemothorax	0	0	0.02
Sepsis, abscesses, endocarditis[a]	1	0.11	0.01
Permanent diaphragmatic paralysis	0	0	0.17
Total femoral pseudoaneurysm	1	0.11	0.93
Total arteriovenous fistula	0	0	0.54
Valve damage/requiring surgery	0	0	0.07
Atrioesophageal fistula	0	0	0.04
Stroke	1	0.11	0.23
Transient ischemic attack	0	0	0.71
Pulmonary vein stenosis requiring intervention	3	0.32	0.29
Vascular access injury complications	2	0.21	–
Total[b]	**13**	**1.39**	**4.5**

The overall risk associated with PVAI in 2016 was 1.39%.

[a]Sepsis, abscesses, and endocarditis requiring surgery were measured.[1] The Cleveland Clinic patient included in the 2016 complications (N = 1) did not require surgery.

[b]The total percentage was calculated by dividing the total number of complications (N = 13) by the total number of PVAI procedures (N = 935). Not represented here is 1 patient with a pulmonary vein stenosis > 70% who did not require intervention.

Reference

1. Cappato R, Calkins H, Chen SA, Davies W, Iesaka Y, Kalman J, Kim YH, Klein G, Natale A, Packer D, Skanes A, Ambrogi F, Biganzoli E. Updated worldwide survey on the methods, efficacy, and safety of catheter ablation for human atrial fibrillation. *Circ Arrhythm Electrophysiol.* 2010 Feb;3(1):32-38.

Pulmonary Vein Stenosis

2010 – 2016

It can take months or years for patients to develop pulmonary vein (PV) stenosis after a PVAI. The table details the incidence of PV stenosis after PVAI from 2010 through 2016, which is consistent with data previously published by Cleveland Clinic.[1] The data are updated annually.

Cleveland Clinic obtains a 3-month postablation CT scan to screen for PV stenosis. Most centers do not screen all PVAI patients for PV stenosis upon follow-up.[2] This may explain the higher percentages of PV stenosis at Cleveland Clinic, as routine screening results in the identification of more cases.

Year of PVAI	PV Stenosis (N)	PVAI Volume (N)	Percent
2010	8	693	1.15
2011	5	776	0.64
2012	7	819	0.85
2013	15	811	1.85
2014	3	772	0.39
2015	5	863	0.58
2016	4	935	0.43
7-year total	**47**	**5669**	**0.83**

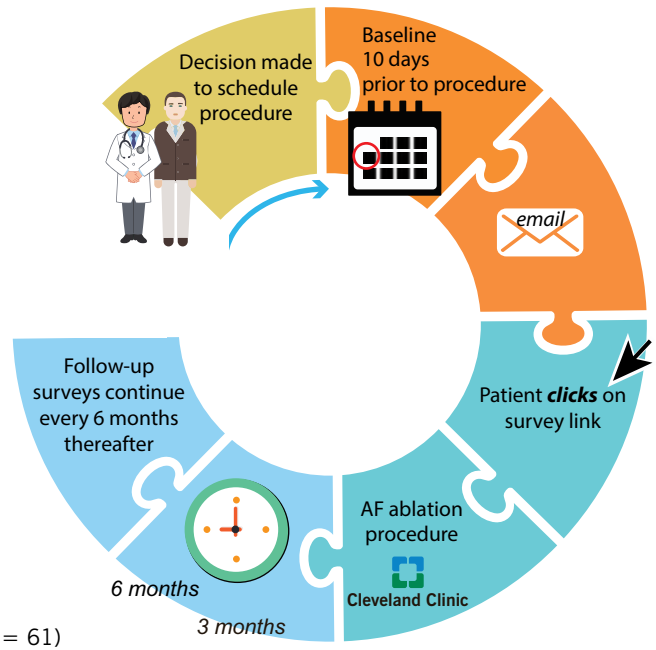
References

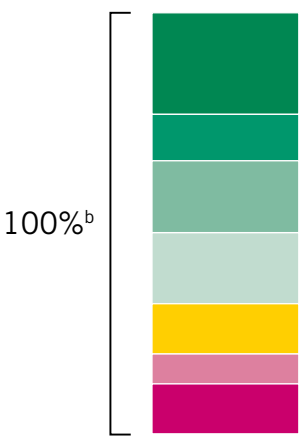
1. Baranowski B, Saliba W. Our approach to management of patients with pulmonary vein stenosis following AF ablation. *J Cardiovasc Electrophysiol.* 2011 Mar;22(3):364-367.
2. Calkins H, Kuck KH, Cappato R, Brugada J, Camm AJ, Chen SA, Crijns HJ, Damiano RJ Jr, Davies DW, DiMarco J, Edgerton J, Ellenbogen K, Ezekowitz MD, Haines DE, Haissaguerre M, Hindricks G, Iesaka Y, Jackman W, Jalife J, Jais P, Kalman J, Keane D, Kim YH, Kirchhof P, Klein G, Kottkamp H, Kumagai K, Lindsay BD, Mansour M, Marchlinski FE, McCarthy PM, Mont JL, Morady F, Nademanee K, Nakagawa H, Natale A, Nattel S, Packer DL, Pappone C, Prystowsky E, Raviele A, Reddy V, Ruskin JN, Shemin RJ, Tsao HM, Wilber D; Heart Rhythm Society Task Force on Catheter and Surgical Ablation of Atrial Fibrillation. 2012 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation: recommendations for patient selection, procedural techniques, patient management and follow-up, definitions, endpoints, and research trial design: a report of the Heart Rhythm Society (HRS) Task Force on Catheter and Surgical Ablation of Atrial Fibrillation. Developed in partnership with the European Heart Rhythm Association (EHRA), a registered branch of the European Society of Cardiology (ESC) and the European Cardiac Arrhythmia Society (ECAS); and in collaboration with the American College of Cardiology (ACC), American Heart Association (AHA), the Asia Pacific Heart Rhythm Society (APHRS), and the Society of Thoracic Surgeons (STS). Endorsed by the governing bodies of the American College of Cardiology Foundation, the American Heart Association, the European Cardiac Arrhythmia Society, the European Heart Rhythm Association, the Society of Thoracic Surgeons, the Asia Pacific Heart Rhythm Society, and the Heart Rhythm Society.

Patient-Reported Outcomes After PVAI

Atrial Fibrillation Tracker (N = 248)[a]

Patient-reported outcomes (PROs) are paramount to assessing disease progression, treatment efficacy, and health-related quality of life (HRQoL). Cleveland Clinic uses a web-based survey system (Atrial Fibrillation Tracker) to collect longitudinal PROs for AF ablation patients. AF symptom severity scores (0–35; higher scores reflect more severe symptoms) are used to measure HRQoL. At 12 months post-PVAI, 69% of patients had an improvement in their AF Symptom Severity Score, ranging from 3–34 points, reflecting an improved HRQoL.





25% very large improvement: ≥ 12 points (N = 61)

11% large improvement: 9 – 11 points (N = 27)

17% moderate improvement: 6 – 8 points (N = 41)

17% small improvement: 3 – 5 points (N = 43)

12% < 3 points (N = 29)

7% same at 12 months (N = 18)

12% worse at 12 months (N = 29)

[a]Data collected from PVAI patients with date of service from November 2013 to January 2017 who completed a baseline, 6-month, and 12-month survey and answered all 7 symptom severity questions.

[b]Percentage totals were rounded.

Reference

1. Interpreting changes in quality of life in atrial fibrillation: how much change is meaningful? Dorian P, Burk C, Mullin CM, Bubien R, Godejohn D, Reynolds MR, Lakkireddy DR, Wimmer AP, Bhandari A, Spertus J. *Am Heart J.* 2013 Aug;166(2):381-387 Epub 2013 Jul 1.

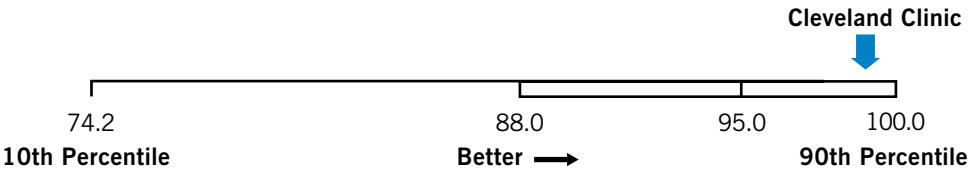
Left Atrial Appendage Occlusion (LAAO)

Patients with atrial fibrillation are at increased risk of stroke due to blood clots that form in the left atrial appendage (LAA). Cleveland Clinic's Atrial Fibrillation Stroke Prevention Center is staffed by specialists who have extensive experience in the use of devices to close off the LAA to reduce this risk. In 2016, 101 patients had LAA occlusion procedures at Cleveland Clinic, with a 99% success rate. The unsuccessful procedure (N = 1) was due to unsuitable LAA anatomy.

Procedures Successful

Rolling Four Quarters Ending 2016 4th Quarter

Cleveland Clinic	US Hospitals 50th Percentile	US Hospitals 90th Percentile
99%	95%	100%



Patients With Any Intra- or Postprocedure Event Prior to Discharge

Rolling Four Quarters Ending 2016 4th Quarter

Cleveland Clinic	US Hospitals 50th Percentile	US Hospitals 90th Percentile
0%	3.4%	0%

Source: National Cardiovascular Data Registry LAAO Registry™

Atrial Fibrillation Stroke Prevention Center

New Medications and Procedures = Reduced Stroke Risk

Cleveland Clinic's Atrial Fibrillation Stroke Prevention Center multidisciplinary team includes specialists in electrophysiology, vascular medicine, gastroenterology, and neurovascular medicine. The goal of the center is to help reduce the risk of stroke among patients with atrial fibrillation who cannot take anticoagulant medications because of a history of bleeding. Patients are evaluated and receive an individualized plan of care that may include medical or interventional treatments.

Ablation of Ventricular Arrhythmia

Volume and Success Rates (N = 231)

2016

Cleveland Clinic is a national referral center for patients with ventricular arrhythmias. In 2016, a total of 231 ablations were done. Partial success means that among patients with multiple arrhythmias, at least 1 arrhythmia was ablated.

	N	Percent
Completely successful	194	84
Partially successful	24	10.4
Unsuccessful	5	2.2
Not targeted	3	1.3
Aborted	5	2.2
Total	**231**	

Complications

A major complication is defined as one that leads to prolongation of hospital stay or to another hospitalization, requires additional intervention for treatment, and/or results in significant injury or death.[1]

Major Complications Among Patients With Ejection Fraction < 50% (N = 125)

Complication	N	Percent
Pericardial effusion with percutaneous intervention	1	0.8

Major Complications Among Patients With Ejection Fraction ≥ 50% (N = 106)

Complication	N	Percent
Pericardial effusion with percutaneous intervention	2	1.89
Stroke	1	0.94
Total	**3**	**2.83**

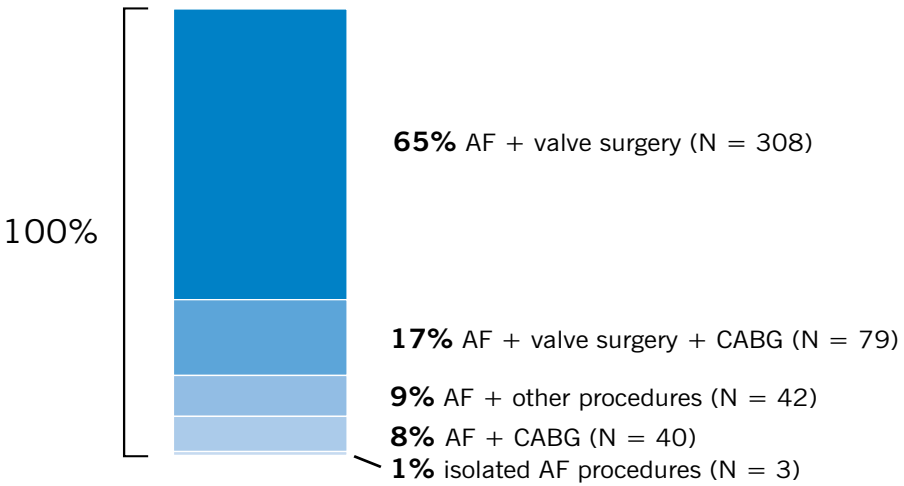
References

1. Aliot EM, Stevenson WG, Almendral-Garrote JM, et al.; European Heart Rhythm Association (EHRA); Registered Branch of the European Society of Cardiology (ESC); Heart Rhythm Society (HRS); American College of Cardiology (ACC); American Heart Association (AHA). EHRA/HRS Expert Consensus on Catheter Ablation of Ventricular Arrhythmias: developed in a partnership with the European Heart Rhythm Association (EHRA), a Registered Branch of the European Society of Cardiology (ESC), and the Heart Rhythm Society (HRS); in collaboration with the American College of Cardiology (ACC) and the American Heart Association (AHA). *Heart Rhythm.* 2009 Jun;6(6):886-933.

Atrial Fibrillation Surgical Procedures

Volume and Type (N = 472)

2016



In 2016, Cleveland Clinic surgeons performed 472 procedures, including minimally invasive approaches, to treat patients with atrial fibrillation.

AF = atrial fibrillation, CABG = coronary artery bypass grafting

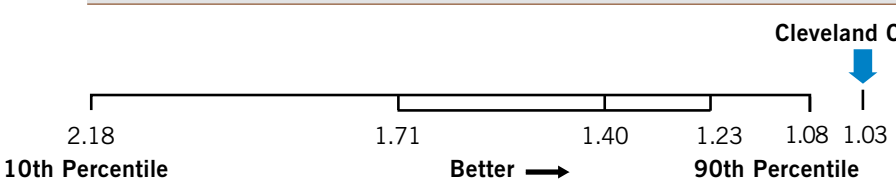
ICD Implants

In-Hospital Risk-Adjusted Complications (N = 716)

Rolling Four Quarters ending 2016 1st Quarter

The in-hospital risk-adjusted complication rate for implantable cardioverter defibrillator (ICD) implants at Cleveland Clinic was 1.03, which represents better outcomes than the all-hospitals 90th and 50th percentiles. Implants include initial implant and generator-change procedures. Exclusions are lead-only procedures, patients who also have epicardial lead implants placed during the procedure, and those who also have lead extractions at the time of implant. Complications include cardiac arrest, coronary venous dissection, device-related infection, myocardial infarction, pneumothorax, emergency cardiac surgery, set screw problems, cardiac perforation, hemothorax, lead dislodgement, pericardial tamponade, transient ischemic attack, hematoma, and death.

Cleveland Clinic	All-Hospitals 50th Percentile	All-Hospitals 90th Percentile
1.03	1.40	1.08



Source: National Cardiovascular Data Registry ICD Registry

Initial Implantation Complications: Pacemaker and ICD[a]

2016

	Pacemaker (N = 445) N (%)	ICD (N = 427) N (%)	Overall (N = 872) N (%)
Complications Measured for 30 Days			
Death	0 (0)	0 (0)	0 (0)
Pneumothorax or hemothorax plus a chest tube	5 (1.12)	1 (0.23)	6 (0.69)
Hematoma plus a blood transfusion or evacuation	0 (0)	0 (0)	0 (0)
Cardiac tamponade or pericardiocentesis	0 (0)	1 (0.23)	1 (0.12)
Complications Measured for 90 Days			
Mechanical complications requiring a system revision	13 (2.92)	7 (1.64)	20 (2.29)
Device-related infection	2 (0.45)	1 (0.23)	3 (0.34)
Additional device implantation	0 (0)	0 (0)	0 (0)
Total[b]	**20 (4.49)**	**10 (2.34)**	**30 (3.44)**

ICD = implantable cardioverter defibrillator

[a]Initial implant: No prior device had been implanted (includes all brady and tachy devices); excludes special devices such as laptop and loop recorders.

[b]Percentage totals were rounded.

Secondary Implantation Complications: Pacemaker and ICD

2016

Procedure Type	N	Major Complications (%)	Benchmark (%)[1]
ICD with lead addition	74	4.05	17.40
ICD without lead addition	172	0.58	5.80
Pacemaker with lead addition	37	0	5.88
Pacemaker without lead addition	145	4.14	2.27

ICD = implantable cardioverter defibrillator

Reference

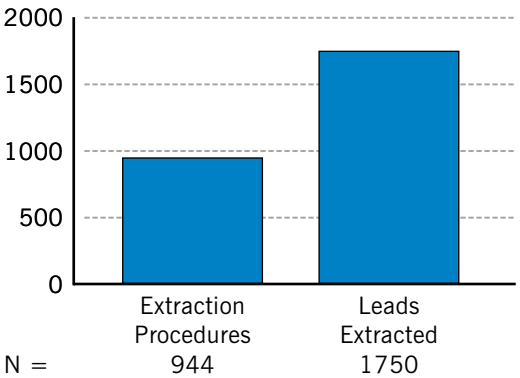
1. Poole JE, Gleva MJ, Mela T, et al.; REPLACE Registry Investigators. Complication rates associated with pacemaker or implantable cardioverter defibrillator generator replacements and upgrade procedures: results from the REPLACE registry. *Circulation*. 2010 Oct 19;122(16):1553-1561.

Lead Extraction Procedures (Leads in Place > 1 Year or Requiring Extraction Technology) (N = 944)

2012 – 2016

Electrophysiologists at Cleveland Clinic perform a high number of lead extractions. In 2016, 1750 leads were extracted during 944 procedures. Many patients have complex conditions that result in referral to Cleveland Clinic physicians. Leads may need removal because of electrical malfunctions, blocked blood vessels, or infection. In most cases, the leads can be removed without opening the chest or heart. Major complications are defined as those causing death or intrathoracic bleeding.

Volume



Clinical success rate[a]	97.6%
Major complications	2.0%

[a]Success is defined as removal of all the required leads without causing bleeding from the veins or heart.

Device Clinic Evaluations Volume (N = 47,970)

2016

Pacemaker evaluations	19,417
ICD evaluations	21,157
Implantable loop recorders	7396

ICD = implantable cardioverter defibrillator

Cleveland Clinic was the first hospital in the country to integrate a patient database for pacemaker and implantable cardioverter defibrillator follow-up with electronic medical records. This innovative approach to follow-up allows staff to keep track of patients' health conditions regardless of the patients' location. Remote monitoring is also associated with increased longevity and decreased need for in-person follow-up.

The institute uses the MyChart® function in Epic, Cleveland Clinic's electronic medical record system, to quickly notify patients of their device status.

2012 – 2016

1.8
average number of leads extracted per procedure

98 months
average lead age at removal

83 months
median lead age at removal